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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/021,338 | 12/12/2001 | Elena Feinstein | 2094/0878/65542/JPW/FHB | 6136 |

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John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

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| EXAMINER |
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MARTINELL, JAMES

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,338

Applicant(s)

FEINSTEIN ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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The Requirement for Restriction (Office action mailed November 4, 2003) is vacated because it clearly does not correspond to the claims in the instant application. The error is regretted.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 13-15, 42, and 43, drawn to polynucleotides, nucleic acid molecular hybridization assays, and antisense agents, classified in class 536, subclasses 23.1 and 23.5 and class 435, subclass 6.
- II. Claims 8-10, drawn to polypeptides, classified in class 530, subclass 350.
- III. Claims 11 and 12, drawn to antibodies, classified in class 530, subclass 387.1.
- IV. Claims 16-19, drawn to methods of screening for neuroprotective compounds comprising no steps, classified in class unknown, subclass unknown.
- V. Claims 20-26, drawn to methods for identifying a compound that inhibits or enhances the activity of a polypeptide, classified in class 536, subclasses 23.1 and 23.5 and class 435, subclass 6.
- VI. Claims 27 and 28, drawn to methods for preparing a composition containing a compound of undisclosed nature, classified in class unknown, subclass unknown.
- VII. Claims 29 and 33, drawn to methods of screening for compounds that induce or inhibit apoptosis, classified in class 435, subclass 4.
- VIII. Claims 36 and 39, drawn to methods of identifying compounds by screening for polynucleotide expression, classified in class 435, subclass 6.
- IX. Claims 40 and 41, drawn to methods of identifying compounds that alter polypeptide activity, classified in class 436, subclass 86.
- X. Claims 44 and 45, drawn to methods of screening for up-regulating or down-regulating drugs comprising no steps, classified in class unknown, subclass unknown.

Claims 30-32, 34, 35, 37, and 38 are ungrouped because they are improper multiple dependent claims.

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The inventions are distinct, each from the other for the following reasons. The polynucleotides and antisense agents of Group I are materially different from and are therefore, independent and distinct from the polypeptides of Group II and the antibodies of Group III. The methods of each of Groups I and IV-X may each be practiced independently of one another. Neither the polypeptides of Group II nor the antibodies of Group III are needed to practice the methods of Group I. The polynucleotides and antisense agent of Group I have uses other than in the methods of Groups IV-X (*e.g.* in affinity chromatography). The polypeptides of Group II are materially different from and are therefore independent and distinct from the antibodies of Group III. The polypeptides of Group II have uses other than in the methods of any one of Groups IV-X (*e.g.*, in affinity chromatography). The antibodies of Group III have uses other than in the methods of any one of Groups IV-X (*e.g.*, in affinity chromatography). The methods of each of Groups IV-X may each be practiced independently of one another.

Claims 1-7, 13-17, 20-22, 29, and 43-45 are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). This notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

Should applicant elect a Group that claims or mentions more than one polynucleotide sequence, applicant is further required to select no more than ONE of the individual sequences for examination. The search of the no more than ONE selected sequence may include the complement of the selected sequence and, where appropriate, may include e subsequences within the selected sequence (*e.g.*, oligomeric probes and/or primers).

Claims 8-12, 20-22, 33, 36, and 39-41 are drawn to large numbers of polypeptides or mention or require the use of large numbers of polypeptides. Should applicant elect a Group that claims or mentions

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more than one polypeptide sequence, applicant is further required to elect one polypeptide sequence within the elected Group for examination on the merits.

To search any two groups as outlined above would create an undue burden for the U.S. PTO because the searches of the non-patent literature are not only non-overlapping to any appreciable extent, but are also divergent in nature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Reminder Regarding *In re Ochiai* and *In re Brouwer*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

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PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is
(703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should
be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.
Primary Examiner
Art Unit 1631**